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Integrated Care for Pregnant Women with Type One Diabetes using Wearable Technology

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Abstract

This paper presents a study into the use of wearable technologies by pregnant women with Type one diabetes (T1D). The World Health Organisation estimates the incidence of T1D globally to be more than 422 million. Wearable technologies can potentially improve decisions around self-management by providing regular feedback on physiological processes. Informed decisions and choices to support self-management of this condition during pregnancy, ultimately enhance pregnancy outcomes. The wearable technologies under consideration include the FreeStyle Libre™ interstitial glucose monitor, Fitbit activity tracker, and blood pressure monitoring for home use. In addition to these devices participants in this research area will be required to maintain a food diary. Physical activity (PA) is recommended during pregnancy to maintain normal blood pressure (BP), physical health and as a preventative measure against deep venous thromboembolism (DVT). Self-reporting of food intake is known to be problematic and is often underestimated. To facilitate assessment of portion sizes participants will be asked to use mobile phone cameras to visually record the type and quantity of food eaten. The collated data will be processed via statistical analysis and computational analysis before providing feedback using machine learning algorithms to inform decisions around the need for insulin or carbohydrate to maintain euglycaemia.

1 Introduction

T1D is an auto-immune condition caused by the destruction of pancreatic β-cells, affecting more than 422 million people globally [1] and impacting pregnancy outcomes [2]. For those living with the condition, regular insulin administration is required for survival [3]. The term 'self-management' encompasses the necessary individual actions performed daily to identify issues and problem-solve, either independently or with the advice of the medical team, to treat and manage an individual's health. This may be done independently or in partnership with healthcare professionals (HCPs) [4].

Approximately 100,000 people in Northern Ireland are known to have diabetes, 10,000 of whom have T1D [5]. T1D affects 1% of all pregnancies in Northern Ireland annually, approximately 85 pregnancies and births. These pregnancies are high risk for mothers and foetuses as shown in (**Figure 1**). Pre-eclampsia, foetal malformation and mortality rates within this population are 2-5 times greater than for non-diabetic populations [2].

The development and use of wearable technologies have improved pregnancy outcomes, particularly maternal glycaemic control [6][7][8].

A review of the literature has identified limited studies investigating the use of wearable technologies, including intermittent glucose monitors (IGM), for participation in regular physical activity (PA) to reduce blood pressure, glycaemic variability, and maternal weight gain within this population [6][7]. The influence of IGM on PA and dietary intake on the cardio-vascular health of pregnant women with T1D using multiple daily injections [6] is an area requiring further research.

Pregnancy guidelines recommend PA as an intervention to reduce the risks of venous thromboembolism and pre-eclampsia [7]. The physiology of T1D impacts rates of success on safely maintaining optimal glucose levels when combining food, exercise and insulin therapy [6], [7]. Activity levels also impact blood glucose levels in various ways. As a result, pregnant women with T1D have concerns around PA and hypoglycaemia [7].

The aim of this research is to investigate the effectiveness of wearable technologies and computational approaches in supporting pregnant women with T1D to achieve optimal PA and euglycaemia with the intention of reducing incidences of maternal pre-eclampsia and neonatal hyper-insulinaemia. This will be achieved through an analysis of heart rate and blood pressure data from activity trackers against IGM data and user inputs of insulin and carbohydrate values. (**Figure 2**).

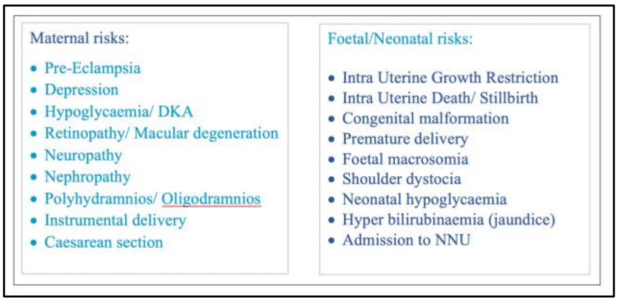

Figure 1 Risks in pregnancies complicated by T1D.

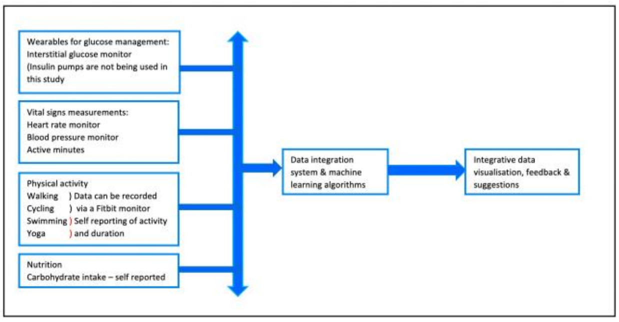

Figure 2 Schematic of intended project design.

Previous studies have explored activity levels, dietary intake and glycaemic variations using closed loop systems [8] but there is a gap in research around the use of IGM and PA by women using multiple daily injections (MDI) [9]. The development of a software integration model combining data including carbohydrate intake, active insulin, activity levels and heart-rate patterns using machine learning to identify patterns in glucose monitoring csv files for ambulatory glucose profiles (AGP) and heart rate patterns within FitBit csv files, for required insulin predictions could potentially be formulated using boundaries within the datasets generated. Decision trees, using a series of 'if-then' statements, could provide a means of reducing the risk of disabling hypoglycaemia or hyperglycaemia for the user [10][11][12]. The development of such software would be beneficial to pregnant women, and others, with diabetes in providing individually tailored information and support with lifestyle choices to facilitate glucose management [12].

2 Wearable Technology

Wearable technologies have an important role in supporting recognised healthy behaviours pertinent to people with T1D, particularly in benefitting cardiovascular health whilst minimising the potential harm of glycaemic variability caused by PA [7][8][10].

The developments within wearable technologies have seen an upsurge in user interest and willingness to access these devices which has been increasingly initiated, recognised, and promoted by HCPs [13]. Technology is a significant adjunct to insulin in managing diabetes and facilitating healthy lifestyle behaviours [9][10] (**Figure 3)**.

Continuous glucose monitors (CGM) and IGM have shown reduced variability in ambulatory glucose profiles of pregnant women with T1D [8][14]. Monitors displaying real-time glucose profiles, with trend arrows identifying increases or reductions in glucose levels, 'smart' glucometers using automated bolus calculators advising users of insulin doses required to maintain euglycaemia, home monitoring devices for blood pressure observation, activity trackers recording step counts and heart rate patterns alongside active minutes per day, which integrate with smartphones to display the information recorded by these devices are, for most people, easily accessible and easy to use [15][16].

Figure 3 shows some of the technology available including glucose monitors, insulin pens and pump technologies which record the date and time of doses administered, and fitness trackers which record HR, active minutes, distances walked or run and calorie output. The information from, for example, Fitbit devices can be accessed from the Cloud and stored as a csv file for further interpretation or investigation [17]. Blood pressure monitoring systems which integrate with smartphones, using Bluetooth connectivity, also have the capacity for data storage in the Cloud and access for analysis by the user [18].

One of the technologies selected for this study is the FreeStyle Libre™ intermittent glucose sensor. This consists of a microneedle filament attached to a base unit which is worn on the upper arm for 14 days. Interstitial fluid glucose readings are recorded every minute in Memory Bank A with one reading from every 15 minutes of wear recorded in Memory Bank B. The datasets generated can be downloaded and stored as csv files. They were added to the British National Formulary as a prescription item in November 2017 and are now available to approximately 60% of people with T1D in Northern Ireland. According to Open Source Data (**Figure 4**), 4,763 prescriptions for the FreeStyle Libre™ sensors were issued across the 5 Health and Social Care Trusts in April 2019. This equates to an approximate 60% uptake of this technology across the province.

Figure 3 Currently available technology hardware

Northern Ireland Freestyle Libre Sensors Prescribed

Freestyle Libre Sensors														
LCG	November	December	January	February	March	April	May	June	July	August	September	October	November 18	December 18
Belfast	26	104	389	542	772	852	1,029	1,264	1,272	1,415	1,540	1,659	1,757	1,745
Northern	47	274	691	812	1,167	1,189	1,553	1,713	1,781	1,852	1,967	2,168	2,194	2,125
South Eastern	16	80	271	352	437	527	681	726	919	1,034	1,060	1,374	1,297	1,368
Southern	14	59	169	328	463	548	561	663	682	763	725	853	938	995
Western	4	151	497	573	843	928	1,119	1,277	1,356	1,470	1,350	1,706	1,598	1,628
Grand Total	**107**	**668**	**2,017**	**2,607**	**3,682**	**4,044**	**4,943**	**5,643**	**6,010**	**6,534**	**6,642**	**7,760**	**7,784**	**7,861**

Northern Ireland Freestyle Libre Prescriptions

Freestyle Libre Prescriptions														
LCG	November	December	January	February	March	April	May	June	July	August	September	October	November 18	December 18
Belfast	12	50	190	290	389	439	516	615	613	691	739	786	832	833
Northern	23	132	337	417	584	613	779	858	884	909	962	1,079	1,093	1,048
South Eastern	5	39	127	170	214	253	325	357	432	497	514	658	633	661
Southern	6	26	84	178	245	293	291	332	351	390	371	425	480	498
Western	2	75	259	300	441	481	574	650	689	744	671	862	810	814
Grand Total	**48**	**322**	**997**	**1,355**	**1,873**	**2,079**	**2,485**	**2,812**	**2,969**	**3,231**	**3,257**	**3,810**	**3,848**	**3,854**

Figure 4 FreeStyle Libre™ prescriptions in Northern Ireland from Open Source Data, courtesy of Nick Cahm

3 Data Collection and Analysis

As previously stated, daily variations in blood glucose patterns are affected by multiple factors including activity levels, hydration, illness, quality of sleep and hormones, notably placental hormones in the case of pregnant women with TID, in addition to the more widely known challenges of carbohydrate and fat intake. Woldergay et al classify the challenges as being of a 'normal cause variation' or a 'special cause variation' [10]. They have identified the development and use of machine learning algorithms for analysing self-collected data produced by users of wearable technologies as an area for further development [10]. They also identify the considerable inter-person differences resulting from those special cause variations as challenges to maintaining euglycaemia, that is to say no formula will produce universal results [10]. Cappon et al report that the increased support from technology in presenting visual displays of data impacts positively on user awareness of glucose management [9].

Choudary et al. [11] and Zhu [12] have shown that using algorithms such as Hidden Markov Model (HMM), Gaussian process regression models or naïve Bayes, collected data can be analysed to identify individual patterns and trends in glucose control during and after physical activity to inform future self-management of glucose levels. Zhu has previously used a HMM to detect anomalies in historical glucose datasets [12]. She acknowledges the potential for incorporating additional physiological datasets including heart rate and blood pressure to detect and predict anomalies into a HMM framework designed for this purpose. She proposes the expansion of observational symbol space to include additional data sets for the detection of anomalies in glucose readings [12]. Decision trees, incorporating 'if-then' statements, could reduce the risk of disabling hypoglycaemia by increasing user awareness of this potential from individualised data sets. This would minimise the need for additional glucose intake by informing decisions around bolus insulin doses when planned increases in BP and heart rate are accounted for, minimise the potential distress [11].

Such a model would benefit pregnant women with T1D by facilitating euglycaemia through the provision of individually tailored information, minimising their risk of hypoglycaemia and increasing cardiac health. The proposed data collection and analysis framework is illustrated in **Figure 5**.

4 Data Integration

An integrative software application, combining data from IGM and activity trackers could inform decisions about food and PA while supporting healthy choices **(Figure 6**). The physiology of pregnancy is recognised as a naturally diabetogenic state [19] with significant hormonal changes initiated by the placenta disrupting the action of insulin and elevating blood glucose levels from the second trimester onwards [19]. Newbern and Freemark identify those hormones disruptive to insulin sensitivity and efficacy as being leptin, placental growth hormone (GH-V) and human placental lactogen (hPL) [20]. GH-V increases maternal insulin resistance, even in non-diabetic pregnancy [20]. The proposed research has a specific application to T1D pregnancy which has an inherent additional burden of GH-V influence, but measurement of this is beyond the scope of this study.

The knowledge gathered from wearables could be combined to inform choices around activity, foods eaten and insulin doses to be administered, further facilitating self-management [21]. Combining the factors of impact of activity levels and heart rate patterns, carbohydrate intake and glucose levels may provide insight into the duration of pregnancy length, the birthweights of babies born to these mothers and their increased risk of hypoglycaemia and jaundice in the first 24 hours after the birth.

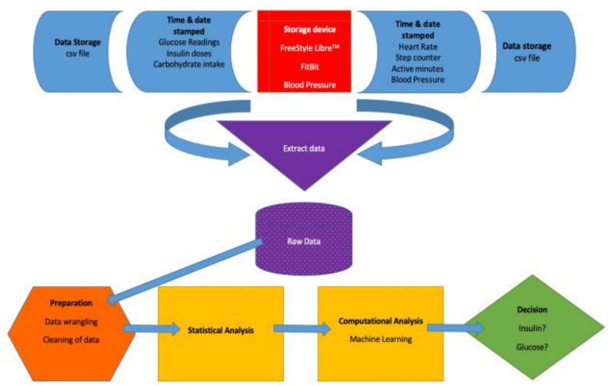

Figure 5 Schematic of proposed data collection and analysis framework.

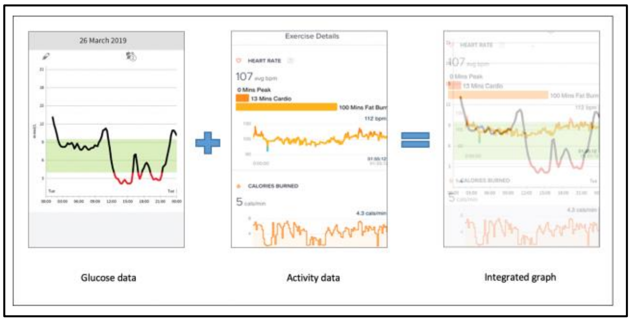

Figure 6 Preliminary diagram of intended visual representation showing combined glucose and HR trends.

5 Summary

Blood glucose predictions, whether they be calculated manually or computationally using algorithms, are based on current blood glucose levels, carbohydrate intake and physiological factors, including hormones and exercise [16]. Access to wearable technology improves glucose control [9], specifically time in target range throughout pregnancy [6]. The concomitant changes to insulin requirements are qualified by feedback provided from monitors and routine capillary glucose samples. There is a significant volume of data generated from IGM, the use of activity & heart rate trackers, and also from capillary glucose monitors. A software system combining the information from IGM, heart rate trackers, BP monitors, food logs etc. into a single platform would provide enhanced information on the impact of these variables and glucose variability [22]. This could provide integrated care and healthier lifestyle choices within this pregnant population. Reducing anxiety around exercise induced hypoglycaemia has the potential to reduce the higher than average incidences of Pre-eclampsia and of optimising neonatal outcomes through the use of an integrative data analysis framework.

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